### Coverage Summary

**Allergy Testing and Allergy Immunotherapy**

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<tr>
<td>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 03/19/2019</td>
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</table>

**Related Medicare Advantage Policy Guidelines:**
- Antigens Prepared for Sublingual Administration (NCD 110.9)
- Challenge Ingestion Food Testing (NCD 110.12)
- Cytotoxic Food Tests (NCD 110.13)
- Food Allergy Testing and Treatment (NCD 110.11)
- Intravenous Histamine Therapy (NCD 30.6)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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### I. COVERAGE

**Coverage Statement:** Allergy testing and allergy immunotherapy (allergy therapy) are covered when Medicare coverage criteria are met.

**Guidelines/Notes:**
1. **Allergy Testing**

   Allergy testing may be covered when Medicare coverage criteria are met.

   *See the Medicare Claims Processing Manual, Chapter 12, §200 - Allergy Testing and Immunotherapy*. (Accessed December 20, 2018)

   Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance
with these policies is required where applicable. These LCDS/LCAs are available at
December 20, 2018)

2. Allergen Immunotherapy
Payment may be made for a reasonable supply of antigens that have been prepared for a
particular patient if:

- the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and
- the physician who prepared the antigens has examined the patient and has determined a
  plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of
medicine or osteopathy or by a properly instructed person (who could be the patient) under the
supervision of the doctor. The associations of allergists that CMS consulted advised that a
reasonable supply of antigens is considered to be not more than a 12-month supply of antigens
that has been prepared for a particular patient at any one time. The purpose of the reasonable
supply limitation is to assure that the antigens retain their potency and effectiveness over the
period in which they are to be administered to the patient. (See §20.2 and §50.2.)

- See the Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1- Antigens. (Accessed
  December 20, 2018)
- Also see the Medicare Claims Processing Manual, Chapter 12, §200 - Allergy Testing and
  Immunotherapy. (Accessed December 20, 2018)
- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and
  compliance with these policies is required where applicable. These LCDs/LCAs are
  available at https://www.cms.gov/medicare-coverage-database/overview-and-quick-

3. Examples of allergy tests/services include but are not limited to:

a. Sublingual antigen; see the NCD for Antigens for Sublingual Administration (110.9).
   (Accessed December 20, 2018)

b. Intravenous histamine administration; see the NCD for Intravenous Histamines (30.6).
   (Accessed December 20, 2018)

c. Routine radioallergosorbent test (RAST)
   - Medicare does not have a National Coverage Determination (NCD) for RAST.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and
     compliance with these policies is required where applicable. For state-specific
     LCDs/LCAs, refer to the LCD Availability Grid (Attachment A).
   - For states with no LCDs/LCAs, refer to the MCG™ Care Guidelines, 23rd edition,
     2019, Quantitative Allergen-Specific IgE Antibody Assays ACG: A-0149 (AC) for
     coverage guideline. (IMPORTANT NOTE: After checking the LCD Availability Grid
     and searching the Medicare Coverage Database, if no state LCD/LCA is found, then
     use the above referenced policy.)
   - Committee approval date: March 19, 2019
   - Accessed August 23, 2019

d. Cytotoxicity testing/Bryan’s test; see the NCD for Cytotoxic Food Tests (110.13).
   (Accessed December 20, 2018)

e. Provocative and neutralizing testing (subcutaneous) for food allergies; see the NCD for
II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

04/01/2019 Updated policy introduction; added language to clarify:
- There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
- In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)

03/19/2019 Re-review with the following update:
Guideline 1.h [Radioallergosorbent Test (RAST) (CPT code 86003 and 86008)] - Updated the MCG™ reference from 22nd edition 2018 to the 23rd edition 2019; no change in MCG™ guideline; no change in the Coverage Summary guideline.

01/15/2019 Annual review with the following updates:
Guideline 1.a – 1.f
- Deleted the following examples (not addressed in the reference Medicare manual):
  a. Complete blood count (CBC) with differential (e.g., eosinophil count, IgE level, smear of nasal secretions)
  b. Chest X-ray, when respiratory symptoms are present
  c. Skin testing
  d. Total gamma globulins
  e. Sputum exam
  f. Paranasal sinus X-ray
- Updated the statement that LCDs are available to a general statement deleting specific LCD titles.
Guideline 1.g (Challenge ingestion food testing) – moved to the new Guideline 3 (Examples of allergy test/services)
Guideline 1.h [Radioallergosorbent Test (RAST) (CPT code 86003 and 86008)] – moved to the new Guideline 3 (Examples of allergy test/services)
Guideline 2 (Allergen Immunotherapy)
- Delete the following (duplicate language in Guideline 3):
  Allergen immunotherapy to treat allergies is covered when:
a. Patient is examined by a physician.
b. The physician who examines the patient, prepares the antigens and develops a plan of care and dosage regimen.

- Delete the following (Medicare reference not found):
  Note: Physician should instruct member on self-administration if member is capable of doing the injections. If a member lives too far from the allergist (rural area) the allergist may prepare the antigens and send the reasonable supply to another physician or qualified healthcare professional for administration.

- Deleted the following duplicate Medicare references:
  See the Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1- Antigens
  Also see the Medicare Claims Processing Manual, Chapter 12, §200 - Allergy Testing and Immunotherapy

  Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See these LCDs for (1) Allergen Immunotherapy, (2) Allergen Skin Testing, (3) Allergy Testing, and (4) Rast Type Tests are available at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.


Guideline 4 – changed to Guideline 3 (Examples of allergy test/services); updated language to read: Examples of allergy tests/services include but are not limited to:

Guideline 4.f – deleted “Urine autoinjection; see the Wisconsin Physicians LCD for Allergy Immunotherapy (L36408)”. (No NCD; current reference is an LCD)

Guideline 4.g – deleted “Skin titration/Rinkel method; see the Wisconsin Physicians LCD for Allergy Testing (L36402).” (No NCD; current reference is an LCD)

Guideline 4.i – deleted “Serum allergy/histamine release tests; see the Wisconsin Physicians LCD for Allergy Testing (L36402).” (No NCD; current reference is an LCD)

03/20/2018 Re-review with the following update:

  Guideline 1.h [Radioallergosorbent Test (RAST) (CPT code 86003 and 86008)]
  - Updated the MCG™ reference from 21st edition 2017 to the 22nd edition 2018;
  - Added CPT code 86008 to guideline title.

01/16/2018 Annual review with the following updates:

  Guideline 4.e (Urine autoinjection) – Added CMS reference.

  Guideline 4.f (Skin titration/Rinkel method) – Added CMS reference.

  Guideline 4.i (Serum allergy/histamine release tests) - Added CMS reference.

03/21/2017 Re-review with the following update:


01/17/2017 Annual review; no updates.

09/20/2016 Re-review with the following updates:
Guideline 1.h [Radioallergosorbent Test (RAST) (CPT code 86003)] -
  o For states with no LCDs replaced current default from the Wisconsin LCD for Allergy Testing and Allergy Immunotherapy (L34597) (retired) with the MCG™ Care Guidelines, 20th edition, 2016, Quantitative Allergen-Specific IgE Antibody Assays ACG: A-0149 (AC).
  o Moved the following language:

Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See LCDs for (1) Allergen Immunotherapy, (2) Allergen Skin Testing, (3) Allergy Testing, and (4) Allergy Testing and Allergy Immunotherapy (5) Rast Type Tests Allergy Tests and (6) at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.” to below Guideline 1.f.

Guideline 2. Note section – Removed reference to the retired LCDs for Allergy Testing and Allergy.

Guideline 3 (Reasonable Supply of Antigen) – Added the following verbiage explaining the definition Reasonable Supply of Antigen and appropriate reference link to the Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1 Antigens:

“Reasonable Supply of Antigen
Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)”

Definitions:
Reasonable Supply of Antigen -Moved to section Guideline 3.
Coverage guidelines of the available LCD align; there is uniformity. There is no applicable UnitedHealthcare Policy available at this time

- **Definitions:**
  - Dose - deleted, unable find CMS reference.
  - Reasonable supply of antigen - Updated definition and added applicable CMS reference.

 02/18/2014 Annual review; no updates.

02/19/2013 Annual review; no updates.

02/27/2012 Annual review; no updates.

08/23/2011 Updated the LCD Availability Grid (Attachment A); deleted retired LCDs, Trailblazer L17419 and Palmetto L5625, L6955, L67882 and L17429.

02/21/2011 Annual review; Updated Guidelines #1.h - Radioallergosorbent Test (RAST) using the standard Coverage Summary language format and using L30471 guidelines for states with no LCDs.

V. ATTACHMENT(S)

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>L3261</td>
<td>Allergy Testing</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<td>L36241</td>
<td>Allergy Testing</td>
<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<tr>
<td>L36402</td>
<td>Allergy Testing</td>
<td>MAC - Part A &amp; B</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>IA, IN, KS, MI, MO, NE</td>
</tr>
<tr>
<td>L36402</td>
<td>Allergy Testing</td>
<td>Mac – Part A</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
<td>AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
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<tr>
<td>L34313</td>
<td>Allergy Testing</td>
<td>A and B MAC</td>
<td>Noridian Healthcare Solutions</td>
<td>CA-NORTHERN, CA-SOUTHERN, AS, GU, HI, MP, NV</td>
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<td>L33591</td>
<td>RAST Type Tests</td>
<td>A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
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<tr>
<td>L34063</td>
<td>RAST Type Tests</td>
<td>MAC - Part A &amp; B</td>
<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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End of Attachment A